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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/199,070 02/22/94 MARASCO

W 43471

EXAMINER  
EISENSCHENK, F

18M2/0919

ART UNIT PAPER NUMBER

5

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1806

DATE MAILED: 09/19/94

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-16 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2. ☐ Claims \_\_\_\_\_ have been cancelled.

3. ☐ Claims \_\_\_\_\_ are allowed.

4. ☐ Claims \_\_\_\_\_ are rejected.

5. ☐ Claims \_\_\_\_\_ are objected to.

6. ☒ Claims 1-16 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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EXAMINER'S ACTION

15. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-16, drawn to nucleic acid delivery systems which introduce DNA into cells and methods of transforming cells in vitro, classified in Class 530, subclass 391.7 and Class 435, subclass 172.3 respectively.
  - II. Claims 1-16, drawn to nucleic acid delivery systems which introduce DNA into cells and methods of in vivo gene therapy, classified in Class 530, subclass 391.7 and Class 514, subclass 44 respectively.
16. Inventions I and II are different methods of use. These inventions require different target cells and process steps to accomplish the desired result for the transformation of cells. Applicants' specification contemplates both in vitro transformation of cells and in vivo gene therapy requiring the introduction of nucleic acid into targeted cells located in a patient. Clearly, differing patentability considerations and enablement issues exist for the in vitro and in vivo methodologies since cells in a culture system are transformed in one system and cells in vivo are transformed in the therapeutic protocols. Therefore they are novel and unobvious in view of each other and are patentably distinct. The product claims will be examined in conjunction with the elected method claims.
17. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-II is not required for any other group from Groups I-II and Groups I-II have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
18. A telephone call was made to Ronald Eisenstein on September 7, 1994 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
20. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in

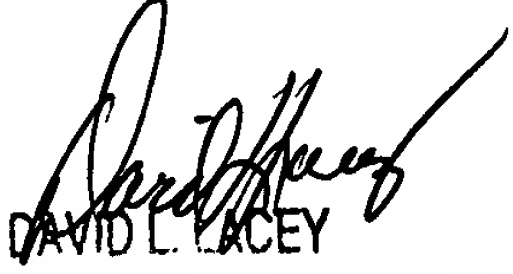
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Art Unit 1806

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the Official Gazette, 1096 OG 30 (November 15, 1989). The CMI Fax Center telephone number is (703) 308-4227.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Eisenschenk whose telephone number is (703) 308-0452. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

Christopher Eisenschenk, Ph.D.  
September 16, 1994

  
DAVID L. LACEY  
SUPERVISORY PATENT EXAMINER  
GROUP 180

9/19/94